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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: M. PUECH

Title: USE OF AN ULTRASONIC TRANSDUCER FOR ECHOGRAPHIC EXPLORATION OF HUMAN OR ANIMAL BODY TISSUES OR ORGANS IN PARTICULAR OF THE EYEBALL POSTERIOR SEGMENT

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DECLARATION OF MICHEL PUECH

Commissioner for Patents
P.O. Box 1450
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Sir:

1. I, the undersigned, Doctor Michel Puech, hereby declare that I am an internationally recognized specialist in the fields of high-frequency ultrasound and ophthalmology. I served for two years as Ophthalmology and High-Frequency Ultrasound Section Chair for the American Institute of Ultrasound in Medicine.

2. In this capacity, I have been in contact with leading specialists in high-frequency ultrasound from around the world. This field of ultrasound was initially developed for ophthalmology, since other medical specialties (gynecology and obstetrics, gastroenterology, urology and nephrology, etc.) use equipment based on 3 to 8 MHz probes which are able to give images of deep-lying organs of the human body.

3. Ultrasound imaging is governed by two concepts:

a. The higher the frequency of the transducer, the greater the resolution of the images, permitting a magnification effect.

b. But the higher the frequency of the transducer, the more the penetration into the tissues is reduced because the ultrasound energy is absorbed and the returning echoes become insufficient to generate an image.

4. The advantage of ultrasound as applied to ophthalmology stems from the superficial location of the eyeballs. From the 1970s, ophthalmology devices were the only ones to use 10 MHz probes for examining the posterior segment of the eyeballs with a resolution superior to conventional ultrasound, which even today still uses probes of 3 to 8 MHz.

5. The works of Charles Pavlin and Stewart Foster in the 1990s were revolutionary in showing that it was possible to obtain images of very high resolution (about 50 microns) using transducers operating at 50 to 80 MHz but with a focus of 4 to 10 mm. These images developed for ophthalmic examination were limited to the anterior part of the eyeball: cornea, anterior chamber and iris (about 4-mm penetration).

6. The team under Jackson Coleman, together with Ron Silverman and Dan Reinstein, developed a research apparatus to examine the anterior segment with still higher resolution; their work was based on transducers comparable to those of C. Pavlin and S. Foster with a frequency of 50 MHz and focus of about 8 to 10 mm for analyzing the cornea, with a measurement precision of about 2 microns by improving the data processing of the signal, but still limited to a penetration of about 4 mm.

7. All of these authors have published works or filed patents specifying that high-frequency ultrasound (50 to 80 MHz) only permitted images with low tissue penetration (about 4 mm), which made the examination of the posterior pole of the eyeball (situated about 23 to 25 mm posterior to the cornea) impossible.

8. My own work was the first to show that the examination of the macula retinae of the human eye was possible with an ultrasound transducer operating at 50 MHz with a 25 mm focus.

9. Examination of deep-lying tissues with a probe operating at a frequency of greater than 20 MHz and with a focus greater than 12 mm represents a technological advance which was considered impossible by some of the most skilled persons in the art. Recognition of this advance based upon my work soon led to the adoption of this new standard by all manufacturers.

10. I therefore declare, in my position as ophthalmologist and research scientist, that a person of ordinary skill in the art would consider the following as true:

A tissue penetration of 4 mm with a probe operating at 50 MHz with a focus of 10 mm (as described by Silverman, Reinstein, Pavlin, Foster) does not anticipate a tissue penetration of 20 to 25 mm with a probe operating at 50 MHz with a focus greater than 12 mm, preferably 20 to 25 mm.

Examination of the anterior segment of the eyeball is completely different from examination of the posterior segment, which is situated deeper and may often be inaccessible by normal examination because of disturbances in the transparent media of the eye (cataract, hemorrhages, etc.). In this case, the advantage of ultrasound is that it passes through optically opaque media to give images of the posterior pole which is inaccessible to visual examination (microscope or laser system).

Examination of the posterior pole using a laser system (as described by Zeimer) uses a monochromatic light totally different from an ultrasound beam. This physical difference between these two energy beams is manifested by the fact that examination of deep-lying tissues by laser beam is possible only when the media traversed by the laser beam are transparent. The eye thus represents a particular case where the retina of the posterior pole can be visualized by laser beam when the media are transparent, but where this

examination is impossible in cases of cataract or intraocular hemorrhage. This difference is even more apparent in cases of examination through opaque tissues such as the skin. No laser system can explore deep-lying organs, as is done in general with ultrasound.

13 Given the fundamental difference in nature between laser beams and ultrasound beams, the system described by Zeimer could not enable one of skill in the art to combine laser imaging of the macula retinae with high-frequency ultrasound imaging.

14. The method described by Chapelon with a probe operating at 3 to 7 MHz and with a focus of 50 mm cannot be combined with Silverman who uses a 50 MHz probe with a 10 mm focus, since it is accepted that the higher the frequency, the more the tissue penetration is reduced, and Silverman describes a method limited to the anterior segment of the eye.

15. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

12/1/04
Date

Michel Pucch